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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

Applicant's arguments filed 01/22/08 have been fully considered but they are not persuasive.

Double Patenting Rejection:

Applicant argues that the double patenting rejection in the instant application is in error because A) the Office Action failed to identify all the differences between the claims of the '626 patent and claim 1 of the instant application and therefore fails to explain why these differences are obvious, and B) for the one difference identified in instant claim 1, the Office Action failed to provide a reason that such a difference is an obvious variation over the scope of the claims of the '626 patent. Applicant argues that claim 1 of the present application recites the transition phrase "comprising" thus allowing the scope of the claim to be open to include other elements, for example, those elements recited in claim 1 of the '626 patent. Applicants note that because of this, the instant claims may be interpreted as "dominating" certain features of the '626 patent claims. MPEP § 804.II provides that domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection. *In re Kaplan,* 789 F.2d 1574, 1577-78, (Fed. Cir. 1986). In other words, even though the claims of the instant application may dominate some claims of the '626 patent, domination, by itself, is not *per se* double patenting. The Office Action must still determine whether the later-filed claims are patentably distinct from the earlier-cited patent claims.

However, in response to applicant's arguments, it is noted that the limitations of dependent claim 18 or 19 support the double patenting rejection. Claim 1 of the '626 patent discloses: a formulation comprising: (a) at least one population of nanoparticulate of at least one poorly soluble active agent having an effective average particle size of less than about 1 micron; (b) at least one surface stabilizer adsorbed onto the surface of the nanoparticulate active agent particles wherein the concentration of the surface stabilizer is from about 0.5% to about 99.999%(w/w), based upon the total weight of the nanoparticulate active agent and the surface stabilizer, and wherein the surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and an ionic surface stabilize; and (c) at least one population of microparticulate active agent, which is either the same as or different from the active agent of (a), and having an effective average particle size of greater than about 1 micron and less than about 10 microns.

Applicant argues the different in the present claims and the claim of the '626 patent is the present of component (c). However, claim 18 of the present application recites: "the composition of claim 1, additionally comprising a meloxicam composition having an effective average particle size which is greater than about 2 microns". Accordingly, the limitations in claim 18 read over component (c) of the '626 patent. Thus, it would have been obvious to one of ordinary skill in the art to prepare the formulation of the '626 patent given the limitations of claims 1 and 18 of the present application. Accordingly, the obviousness-type double patenting rejection is maintained.

103(a) rejections:

Applicant argues that the office fails to provide support for its finding that the claimed release profiles are inherent properties. The rejections are based upon a combination of references, which combination is acknowledge by the Examiner as failing to teach or suggest all the elements of the claimed invention, namely, the release profiles. The final Office Action has maintained the obviousness rejection alleging that the missing claimed release profiles are inherent in the prior art composition. The final Office Action provides two statements, discussed in detail above, as supporting its conclusion that the claimed release profiles are inherent in the prior art. Applicants have shown that the invention does not exist in the prior art, but for a hindsight construction based upon a combination of references. Applicants have also shown, and provided instructive BPAI decisions, that the additional statements supplied by the final Office Action are insufficient to shift the burden to the Applicants to show that the claimed release profiles are not inherent.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Further, in response to applicant's argument regarding the release profiles, it is noted that independent claims 26 and 50 do not require any specific release profile. Moreover, while the present claim 1 recites the composition exhibits a shorter time to T_{max} when compared to the time to T_{max} of the non-nanoparticulate meloxicam formulation, the showing in the present specification does not provide a reasonable comparison. See for example page 48 of the present specification, which concludes that "the nanoparticulate meloxicam formulations resulted in faster dissolution, thereby producing a much shorter T_{max} (0.75 and 1.3 hours, respectively, for Formulations #1 and #2, as compared to 3.4 hours for Formulation #3)". However, dissolution rates can be different depend in different formulations for each dosage form. This is evident by the showing in the present specification. Formulation #1 is a liquid dispersion using the present nanoparticulate, which showed a faster dissolution rate and therefore, a shorter T_{max}. Formulation #2 is a lyophilized wafer that also utilized the present nanoparticulate, but showed a slower dissolution rate, and therefore, exhibits a longer T_{max}. The specification is then comparing these two formulations with a tablet dosage form to show that the tablet exhibits a longer T_{max}. Each of these three dosage forms exhibit different T_{max}, with the fastest T_{max} being a liquid formulation. The formulation of the tablet is not disclosed by the present specification. Accordingly, the examiner is unable to determine unexpected result and patentability of the present application because the comparison data did not show a compatible formulation for each dosage form. It is noted that objective evidence of nonobviousness must be commensurate in scope with claims that evidence is offered to support. See in *Greenfield and DuPont* 197

USPQ 227 (CCPA 1978); *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980); and *In re Tiffin and Erdman* 170 USPQ 88 (CCP 1971). Thus, the 103(a) rejections are maintained.

/S. Tran/
Primary Examiner
Art Unit 1618